Guidance Beyond the SDTM Implementation Guide

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Agenda

1. Introduction
2. CDISC Guidance
3. PHUSE Guidance
4. Regulatory Guidance
5. Other Guidance
6. Impact of Disregarding Available Guidance
7. Conclusion

Introduction

- When preparing SDTM datasets for submission, further guidance may be needed to fill in some of the gaps that are not outlined in the SDTM Model or the SDTM Implementation Guide (SDTMIG)
- Regulatory requirements must also be followed that may differ from what is in the CDISC standards
- Clarifying information is needed but it can be difficult to determine if such documentation exists and where to find it
- Substantial guidance has been published from many different sources (e.g., CDISC, regulatory authorities, etc) to aid implementers in preparing submission deliverables

CDISC Guidance

CDISC THERAPEUTIC AREA USER GUIDES

- Though the SDTMIG covers much of the data commonly collected in clinical trials, there are some gaps, mostly due to data specific to certain therapeutic areas (TA)
- CDISC Therapeutic Area User Guides (TAUGs) were developed to fill some of these gaps
- Each TAUG contains information specific to a therapeutic area as well as examples of the type of data that might be collected in a study
- All TAUGs contain SDTM examples and most also contain CDASH-compliant CRF representations as well as ADaM guidance
- Most new standards content, such as new variables and SDTM domains, have first appeared in TAUGs
- Like the IGs, each TAUG's content is consensus-based, meaning that each must go through both Internal and Public Review before it can be published

CDISC Guidance

CDISC THERAPEUTIC AREA USER GUIDES

- Published TAUGs are considered ‘Provisional’ due to new variables and domains that have not yet been added to the SDTM/SDTMIG
- Examples in TAUGs are considered ‘informative’ content vs ‘normative’ content
- When modeling data based on TAUG examples, any new variables should be mapped as non-standard variables (NSVs), i.e. SUPPQUAL
- New domains based on one of the 3 general observation classes are considered custom domains
  - NOTE: Custom Special-Purpose domains are not permitted per the guidance in the SDTMIG
- New versions of the same TAUG will supersede the previous version
  - Vaccines TAUG v1.1 should be referenced versus v1.0

CDISC Guidance

CDISC THERAPEUTIC AREA USER GUIDES

- If a TAUG was used for a study, the specific TAUG referenced should be listed in the Trial Summary (TS) domain (TSPARM/TSPARMCD = 'CTAUG'/'CDISC Therapeutic Area User Guide')
  - Listed in the FDA Study Data Technical Conformance Guide (sdTCG), Appendix B:

Conditional	CTAUG	CDISC Therapeutic Area User Guide	If applicable. the value should be the exact listing as in section 5.2 of the Technical Conformance Guide. Use as many rows as needed.

- FDA sdTCG, Section 5.2 lists those TAUGs that have been evaluated and supported by FDA
  - If the TAUG used is not listed, the rationale should be explained in the Clinical Study Data Reviewer's Guide (cSDRG)
- In addition to the TAUG names in the sdTCG, there is a CTAUGRS (CDISC Therapeutic Area User Guide Response) codelist in SDTM CT that can be used to populate TSVAL

CDISC Guidance

CDISC THERAPEUTIC AREA USER GUIDES

- Acute Kidney Injury
- Alzheimer's
- Asthma
- Breast Cancer
- Cardiovascular
- CDAD
- Colorectal Cancer
- COPD
- COVID-19
- Crohn's Disease
- Diabetes
- Diabetes Type 1 - Exercise and Nutrition
- Diabetes Type 1 - Pediatrics and Devices
- Diabetes Type 1 - Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes
- Diabetic Kidney Disease
- Duchenne Muscular Dystrophy
- Dyslipidemia
- Ebola
- Heart Failure
- Hepatitis C
- HIV
- Huntington's Disease
- Influenza
- Kidney Transplant
- Lung Cancer
- Major Depressive Disorder
- Malaria
- Multiple Sclerosis
- Nutrition
- Pain
- Pancreatic Cancer
- Parkinson's Disease
- Pediatrics
- Polycystic Kidney Disease
- Post Traumatic Stress Disorder
- Prostate Cancer
- Psoriasis
- QT Studies
- Rare Diseases
- Rheumatoid Arthritis
- Schizophrenia
- Traditional Chinese Medicine - Acupuncture
- Traditional Chinese Medicine - Coronary Artery Disease-Angina
- Traumatic Brain Injury
- Tuberculosis
- Vaccines
- Virology

- Any CDISC TAUG used in this list should be compared to Section 5.2 in the sdTCG

https://www.cdisc.org/standards/therapeutic-areas

CDISC Guidance

QUESTIONNAIRES, RATINGS AND SCALES (QRS) SUPPLEMENTS

- Contain information about the instrument as well as guidance and examples for representing the data in SDTM
- Useful in mapping to the appropriate domain and properly structuring the data
  - Questionnaires (QS)
  - Functional Tests (FT)
  - Clinical Classifications and Disease Response (RS)
- Each TAUG lists QRS instruments that may be used for a specific TA as well as the status of the CDISC QRS supplement, e.g. 'In Progress', 'Final', etc
- Like TAUGs, QRS supplements go through Internal and Public Review
- When authored, the most recent version of the SDTMIG is used but are considered to be version agnostic

https://www.cdisc.org/standards/foundational/qrs#qrs__supplements

CDISC Guidance

QUESTIONNAIRES, RATINGS AND SCALES (QRS) SUPPLEMENTS

RS = Disease Response and Clin Classification

RSCAT=ECOG

ECOG PERFORMANCE STATUS

	Grade	ECOG
☐	0	Fully active, able to carry on all pre-disease performance without restriction
☐	1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
☐	2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
☐	3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
☐	4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
☐	5	Dead

RSSTRESC/RSSTRESN

RSORRES when RSTESTCD = ECOG101

CDISC believes this instrument to be in the public domain, but you should perform your own assessment. CDISC specifies how to structure the data that has been collected in a database, not what should be collected or how to conduct clinical assessments or protocols.

The ECOG uses a single-status assessment that clinicians may use to evaluate a patient's disease progression, the effect of the disease on daily living abilities, and appropriate treatment and prognosis.

1. The scale point includes a numeric rating (0-5) and a definition of what is represented by the rating (e.g., 0 = "Fully active, able to carry on all pre-disease performance without restriction"). For the ECOG, RSORRES is populated with the text description while the numeric rating is represented in the standardized character and numeric result variables RSSTRESC and RSSTRESN.

3.2 Example for the ECOG RS Domain Model

The ECOG example below shows the terminology used to implement the instrument in the RS domain. This example shows the data for 3 subjects collected at two visits for an ECOG instrument. The example uses CDISC Controlled Terminology for RSTESTCD, RSTEST, and RSCAT. All original results are represented with preferred terminology in RSORRES. This result is then transformed into the standard numeric score in RSSTRESN and a character representation of the standard numeric score in RSSTRESC.

The table represents the item from the ECOG instrument. The subjects did not fill out the instrument at VISITNUM = 2, so all items are represented as missing.

rs.xpt

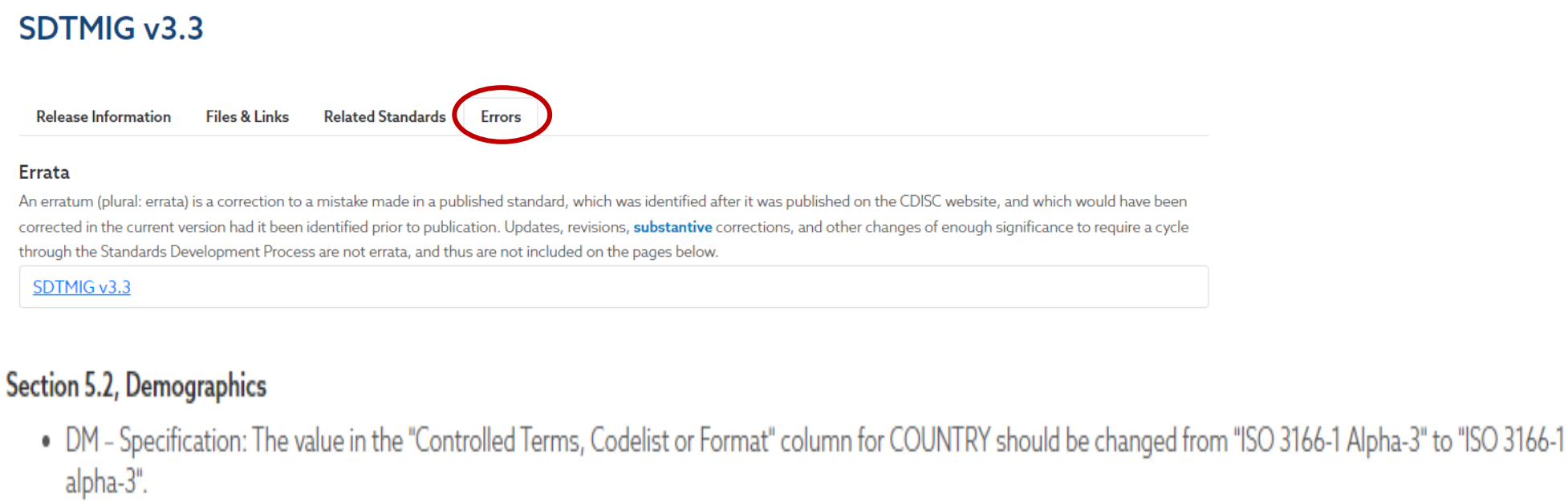
Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	RSSTRESN	RSSTAT	RSLOBXFL	VISITNUM	RSDTC
1	STUDY001	RS	001-001	1	ECOG101	ECOG1-Performance Status	ECOG	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours	3	3		Y	1	2013-04-09
2	STUDY001	RS	001-001	2	ECOG101	ECOG1-Performance Status	ECOG				NOT DONE		2	2013-05-09
3	STUDY001	RS	001-002	1	ECOG101	ECOG1-Performance Status	ECOG	Fully active, able to carry on all pre-disease performance without restriction	0	0		Y	1	2013-04-09
4	STUDY001	RS	001-002	2	ECOG101	ECOG1-Performance Status	ECOG				NOT DONE		2	2013-05-09
5	STUDY001	RS	001-003	1	ECOG101	ECOG1-Performance Status	ECOG	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work	1	1		Y	1	2013-04-10
6	STUDY001	RS	001-003	2	ECOG101	ECOG1-Performance Status	ECOG				NOT DONE		2	2013-05-10

https://www.cdisc.org/standards/foundational/qrs#qrs__supplements

CDISC Guidance

SDTMIG ERRATA

- Sometimes errors are identified after the SDTMIG is published
- Errata are located on the CDISC website and kept on the page for that specific version of the SDTMIG under the ‘Errors’ tab



https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3

CDISC Guidance

SDTMIG ERRORS THAT AFFECT CONFORMANCE

- If an error would appear in validation, it is published as an ‘Error that Affects Conformance’ and not an ‘Errata’
  - Also located on the ‘Errors’ tab for that specific version of the SDTMIG
- The issue is described and coping strategies for handling the error in the standard are provided
  - A coping strategy may include simply explaining the issue in the cSDRG
- Please note that the error is not formally corrected in that version of the SDTMIG, i.e., the standard is not changed

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3

CDISC Guidance

SDTMIG ERRORS THAT AFFECT CONFORMANCE

DSDY should be "Permissible", not "Expected"

Short Name	DSDY should be permissible, not expected
Affected Standard	SDTMIG v3.3
Description of Error	In the DS domain specification, the core value of DSDTC is "Perm" but the core value of the corresponding study day variable, DSDY, is "Exp". The study day variable corresponding to a date/time variable that is "Perm" cannot be "Exp". Note that DSDY was not included in the DS doman specification in previous versions of the SDTMIG.
Efforts to Correct Error	The core value for DSDY will be changed to be "Perm" in the next version of the SDTMIG.
JIRA Issue	SDS-1417

Concerned Published Element	Concerned Published Attribute	Published Attribute Value	Revised Attribute Value
DS.DSDY	Core	Exp	Perm

Impact of Issue	Coping Strategy
If DSDTC was not collected, so that DSDY is always null, failure to include DSDY in the DS dataset may result in errors or warnings.	Explain any validation errors or warnings in the Clinical Study Data Reviewers Guide (cSDRG).

- If DSDY is not included in DS:
  - SD0057 – SDTM Expected Variable not found
- If DSDY is included in DS:
  - SD1149 - Expected variable with missing value for all records
- Regardless of the approach, this would need to be explained in the cSDRG

https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3

CDISC Guidance

OTHER GUIDANCE FROM CDISC

- SDTMIG – Associated Persons v1.0
- SDTMIG – Medical Devices v1.1
- Knowledge Base (KB) - https://www.cdisc.org/kb
  - Useful articles, Known Issues, Examples Collection, example CRFs in the eCRF Portal
- Define-XML v2.0 and v2.1
  - Both versions are currently supported by FDA
- SDTM Metadata Submission Guidelines (MSG) v2.0
  - Guidance for preparing the different components required for a submission: Annotated Case Report Form (aCRF), SAS v5 XPT files, define.xml, and the cSDRG
  - Informative rather than normative content and should be used in conjunction with CDISC standards
  - An example submission package is included

PHUSE Guidance

BEST PRACTICES FOR SUBMISSION OF EVENT ADJUDICATION DATA

- Provides guidance for handling adjudication data in SDTM
- Adjudication is a committee's blinded evaluation of specific endpoints/events in a clinical trial
- The events that are reviewed are typically subjects' adverse event data collected in a study
- CDISC TAUGs provide some guidance and examples but not enough
- Proposal to standardize how this data is submitted so that sponsors can follow one approach that would help create consistency across industry

PHUSE Guidance

BEST PRACTICES FOR SUBMISSION OF EVENT ADJUDICATION DATA

- Event Adjudication (EA) domain

STUDYID	USUBJID	DOMAIN	EALNKID	EAREFID	EAREPNUM	EASTEST	EATESTCD	EAOBJ	EACAT	EAORRES	EAEVAL	EAEVALID	EAACPTFL	EADTC
STUDY01	100100	EA	14	1	1	ADJOUT	Adjudication outcome	ACS	FIRST ADJUDICATION	ACUTE MYOCARDIAL INFARCTION	ADJUDICATOR	ADJUDICATOR 1		2017-04-04
STUDY01	100100	EA	14	1	1	ADJDATE	Evaluated Event Onset date	ACS	FIRST ADJUDICATION	2017-01-01	ADJUDICATOR	ADJUDICATOR 1		2017-04-04
STUDY01	100100	EA	14	1	1	MICLASS	Classification of Myocardial Infarction	ACS	FIRST ADJUDICATION	ST ELEVATION MYOCARDIAL INFARCTION	ADJUDICATOR	ADJUDICATOR 1		2017-04-04
STUDY01	100100	EA	14	1	1	MITYPE	Type of Myocardial Infarction	ACS	FIRST ADJUDICATION	TYPE 1 MYOCARDIAL INFARCTION	ADJUDICATOR	ADJUDICATOR 1		2017-04-04
STUDY01	100100	EA	14	1	1	CONFEVT	Confirmation of event	ACS	FIRST ADJUDICATION	FULL DOCUMENT AVAILABLE	ADJUDICATOR	ADJUDICATOR 1		2017-04-04
STUDY01	100100	EA	14	1	2	ADJOUT	Adjudication outcome	ACS	FIRST ADJUDICATION	ACUTE MYOCARDIAL INFARCTION	ADJUDICATOR	ADJUDICATOR 2		2017-04-10

- Will be published in SDTMIG v4.0 to make EA a standard Findings About-structured domain

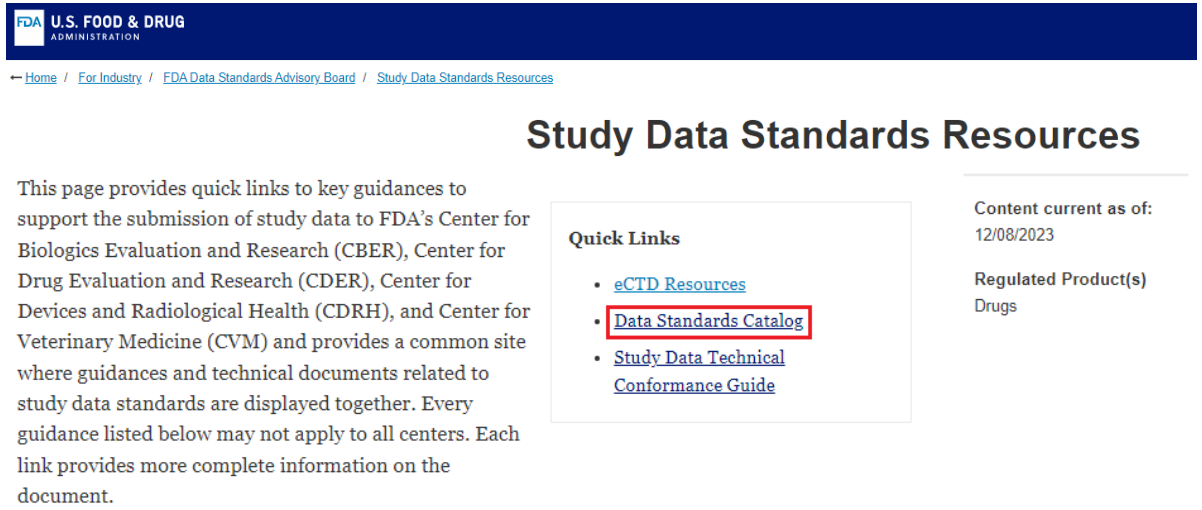
PHUSE Guidance

OTHER GUIDANCE FROM PHUSE

- Define-XML v2.0 Completion Guidelines
  - Clarifies some of the more challenging metadata items in the define.xml file
  - Not meant repeat what is already outlined in CDISC's Define-XML standard
  - Geared towards Define-XML v2.0 but could also be applied to Define-XML v2.1
- Best Practices for Documenting Dataset Metadata: Define-XML Versus Reviewer's Guide
  - Guidance on documenting the dataset metadata for a trial with recommendations on where to best add this information: define.xml vs cSDRG
  - Best practices for explaining validation results in the cSDRG

Regulatory Guidance

DATA STANDARDS CATALOGS



Notable Differences:

- SEND - FDA lists many versions as supported, but PMDA lists none
- SDTM - FDA lists new(ish) v3.4 as supported, but latest version supported by PMDA is v3.3
- ADaM – FDA lists versions 1.2 and 1.3 as supported, but latest version supported by PMDA is v1.1
- DEFINE-XML - FDA lists version 2.1 as supported, but latest version supported by PMDA is v2.0

Regulatory Guidance

STUDY DATA TECHNICAL CONFORMANCE GUIDES AND FAQS

- FDA's Study Data Technical Conformance Guide

1.2 Purpose

This Guide provides technical recommendations to sponsors[4] for the submission of animal and human study data and related information in a standardized electronic format in INDs, NDAs, ANDAs, and BLAs.[5] The Guide is intended to complement and promote interactions between sponsors and FDA review divisions. However, it is not intended to replace the need for sponsors to communicate directly with review divisions regarding implementation approaches or issues relating to data standards.

- PMDA's Technical Conformance Guide on Electronic Study Data Submissions

1.1 Purpose

Handling of the submission of electronic study data for new drug applications has been described in the notification on gateway application, notification on electronic study data and its question and answer guide. More detailed matters and precautions regarding the submission of electronic study data are provided in this guide.

In addition, detailed matters and precautions concerning the submission of related electronic files, including the eCTD, shall be described together in this guide.

- PMDA's FAQs on Electronic Study Data Submission

FAQs on Electronic Study Data Submission

This document summarizes inquiries on electronic study data submission received by the PMDA in a Q&A format.

Regulatory Guidance

TECHNICAL SPECIFICATION DOCUMENTS

5.3 List of FDA Technical Specification Documents

Technical specification documents provide detailed information for content on specific topics, where applicable, submitted to FDA for an application. Sponsors should consult with the review division early in the process to discuss issues with trial design or conduct that may affect the content of the study data being submitted. Technical specifications can be found here.[51]

- **5.3.1 Submitting Nonclinical Datasets for Evaluation of Rodent Carcinogenicity Studies of Parmaceuticals, Guidance for Industry** SEND guidance
- **5.3.2 Submitting Next Generation Sequencing Data to the Division of Antiviral Products** Data Collection and Reporting guidance
- **5.3.3 Submitting Clinical Trial Datasets for Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential of Drugs** ADaM guidance
- **5.3.4 Bioanalytical Methods Templates** Summary Table guidance
- **5.3.5 Submitting Select Clinical Trial Data Sets for Drugs Intended to Treat Human Immunodeficiency Virus-1 Infection** ADaM guidance
- ✔ **5.3.6 Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review** SDTM guidance
- **5.3.7 Technical Specifications-Comparative Clinical Endpoint Bioequivalence Study Analysis Datasets for Abbreviated New Drug Applications** ADaM guidance
- ✔ **5.3.8 Technical Specifications for Submitting Clinical Trial Data Sets for Treatment of Noncirrhotic Nonalcoholic Steatohepatitis (NASH)** SDTM (and ADaM) guidance
- ✔ **5.3.9 Submitting Patient-Reported Outcome Data in Cancer Clinical Trials** SDTM (and ADaM) guidance
- ✔ **5.3.10 Submitting Clinical Trial Datasets and Documentation for Clinical Outcome Assessment Using Item Response Theory** SDTM (and ADaM) guidance

*From the FDA's Study Data Technical Conformance Guide, December 2023

Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review

- Reactogenicity Data, Unsolicited AEs, Lab Assessments, MAAEs, Deaths
- Clinical Disease Endpoint Efficacy Data
- Immunogenicity, Concomitant Medication, Maternal Immunization Data

Submitting Clinical Trial Data Sets for Treatment of NASH

- Guidance for SDTM domains: BE, BS, MI/SUPPMI, RS, ZI, ZA, and others
- Guidance for ADaM datasets: ADSL, ADAE, ADLB, ADDILI, ADMI, ADRS, ADTTE

Submitting Patient Reported Outcome Data in Cancer Clinical Trials

- Guidance for SDTM domains: QS, TS
- Guidance for ADaM datasets: ADQS
- Handling of missing PRO data, data not collected due to skip logic or CAT
- Guidance for tables and figures

Submitting Clinical Trial Datasets and Documentation for COAs Using IRT

- Guidance for SDTM domains: ZQ (item dataset), QS, TS
- Guidance for ADaM datasets: ADQS
- Handling of missing data, data not collected due to skip logic or CAT

Other Guidance

HOW TO USE WHODRUG FOR COMPLIANCE WITH CM DOMAIN IN THE SDTM STANDARD

Background

The CDISC SDTM (Study Data Tabulation Model) standard describes how to report data from a clinical trial and includes guidance for reporting of concomitant medications. The CDISC implementation guide does not state how to retrieve the concomitant medication data from a drug dictionary; this guide aims to give data managers and SAS programmers detailed information for how to retrieve the correct data from WHODrug for inclusion in the Concomitant medication (CM) domain and as a result be fully compliant with the CDSIC SDTM standard.

This guide is based on the CDISC SDTM standard version 1.4[1] and implementation guide version 3.2. There are five variables within the CM domain that are most relevant with relation to WHODrug: CMTRT, CMMODIFY, CMDECOD, CMCLAS and CMCLASCD.

Impact of Disregarding Available Guidance

DISREGARDING REGULATORY GUIDANCE

Guidance for Industry

Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act

IV. ISSUANCE AND USE OF INFORMATION REQUEST AND DISCIPLINE REVIEW LETTERS

A. General

CBER and CDER will use IR letters to obtain clarifying information to assist in completing a review. Because the Agency issues IRs to obtain clarification, it is normally expected that the applicant will respond as quickly as possible. FDA reviews such responses (if they are of a clarifying nature) as part of the current review cycle of the application. However, if the response is of a significant nature, the response could constitute a major amendment. Major amendments to an original application received in the last three months of the review cycle may extend the Action Due date by three months. Only one such extension is permitted. FDA may defer the review of a response to the next review cycle, if the review team believes that the new information cannot be fully reviewed in the time remaining in the current review cycle or is ready to issue an action letter.

Impact of Disregarding Available Guidance

DISREGARDING SDTMIG ERRATA AND ERRORS THAT AFFECT CONFORMANCE

Errors that Affect Conformance

Core Values for MIBLFL, MILOBXFL, MOBLFL, and MOLOBXFL

Short Name	Core Values for MIBLFL, MILOBXFL, MOBLFL, and MOLOBXFL
Affected Standard	SDTMIG v3.3
Description of Error	The --LOBXFL (Last Observation before Exposure) variable was introduced as a Findings Domain qualifier with the intent of eventually replacing --BLFL (Baseline Flag). In findings domains in which --BLFL was expected, its core value was to be changed to permissible, while --LOBXFL became expected. This was not carried out as intended for the MI (Microscopic) and MO (Morphology) domains. In the MI domain, MIBLFL is expected but should be permissible and MILOBXFL is permissible but should be expected. In the MO domain, MOBLFL is expected but should be permissible and MOLOBXFL is permissible but should be expected.
Efforts to Correct Error	The core values will be corrected in the next version of the SDTMIG.

Sponsor explanation for resulting validation issue:

4.2 Issues Summary

Check ID	Diagnostic Message	Dataset	Count (Issue Rate)	Explanation
SD0057	SDTM Expected variable MILOBXFL not found	MI	1 (100.00%)	MILOBXFL is a permissible variable in SDTMIG 3.3. Pinnacle 21 is flagging this incorrectly.

False explanation

Impact of Disregarding Available Guidance

DISREGARDING UPPSALA MONITORING CENTRE GUIDANCE

CMDECOD is longer than 200 characters

For drugs with many ingredients, the generic name is longer than 200 characters. The SAS export format has a limitation to 200 characters per field, if this format is used for submission, the supplemental dataset needs to be utilised. Note that the guidelines state that the text should be truncated between words, in the case for long generic names the text should be truncated after the semicolon closest to 200 characters. Illustrations of the ordinary and supplemental datasets are shown in table 1 and 2.

This guidance from Uppsala Monitoring Centre

Table 1. Illustration of SDTM dataset where CMDECOD is longer than 200 characters.

USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	CMCLAS	CMCLASCD
AB-21-01	1	....	...	Ascorbic acid;Biotin;Calcium;Carbohydrates nos; Chloride;Choline;Chromium;Colecalciferol; Copper;Cyanocobalamin;Docosahexaenoic acid; Fats nos;Folic acid;Fructooligosaccharides; Iodine;Iron;Magnesium;	....	....

Table 2. Illustration of supplemental dataset for CM domain where CMDECOD is longer than 200 characters.

USUBJID	RDOMAIN	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
AB-21-01	CM	CMSEQ	1	CMDECOD1	Standardized Medication Name 1	Manganese;Nicotinic acid;Pantothenic acid;Phosphorus;Phytomenadione; Potassium;Proteins nos;Pyridoxine; Retinol;Riboflavin;Selenium;Sodium; Thiamine;Vitamin e nos;Zinc

Is used in this validation rule algorithm

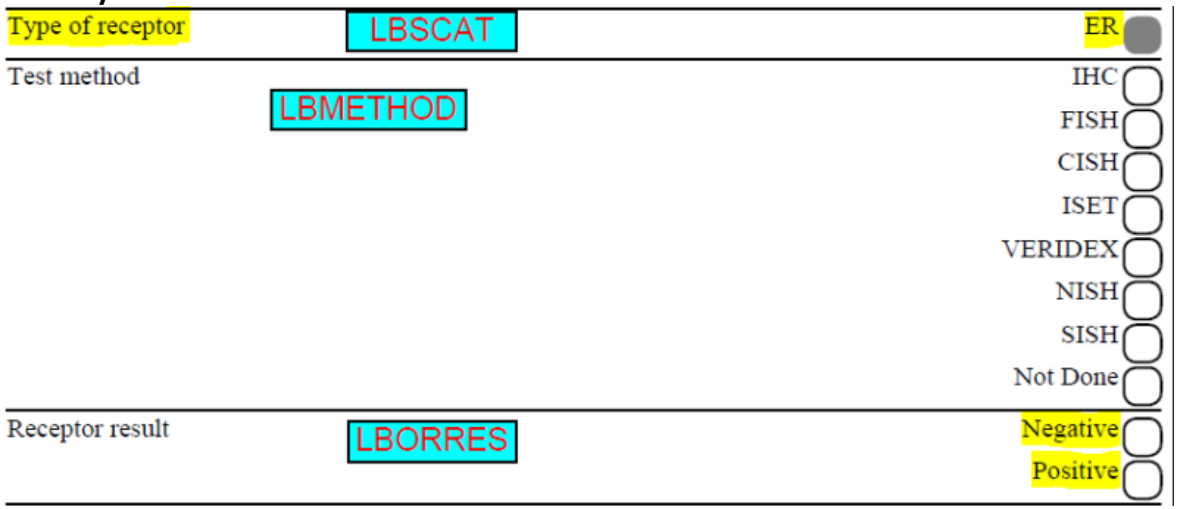
version 1.6, finalized December 2022

FDA Validator Rule ID	Publisher	Publisher ID	FDA Validator Rule Message	FDA Validator Rule Description
SD1344	FDA	FDAB017	Value for --DECOD not found in WHODrug dictionary	Value for the Standardized Medication Name (--DECOD) variable must be populated using a Drug Name from the WHO Drug dictionary version specified in the define.xml.

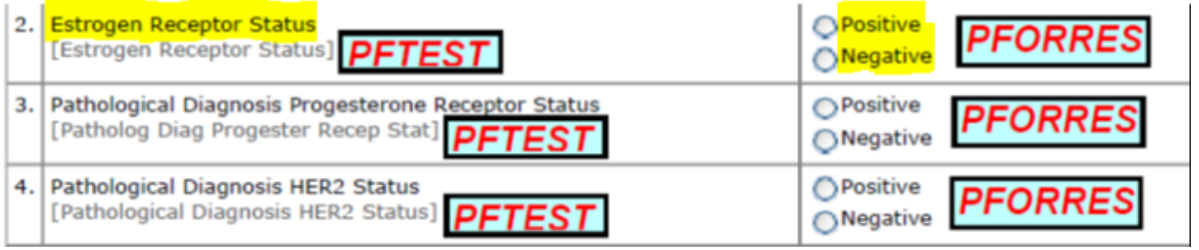
Impact of Disregarding Available Guidance

DISREGARDING CDISC TAUGS AND PHUSE GUIDANCE

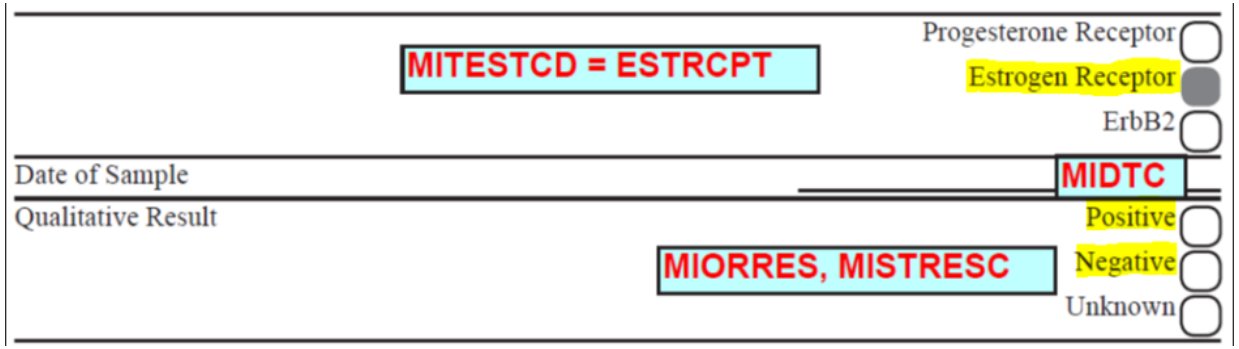
✖ Study 1:



✖ Study 2:



✔ Study 3 (This is the approach that matches the example in the Breast Cancer TAUG):



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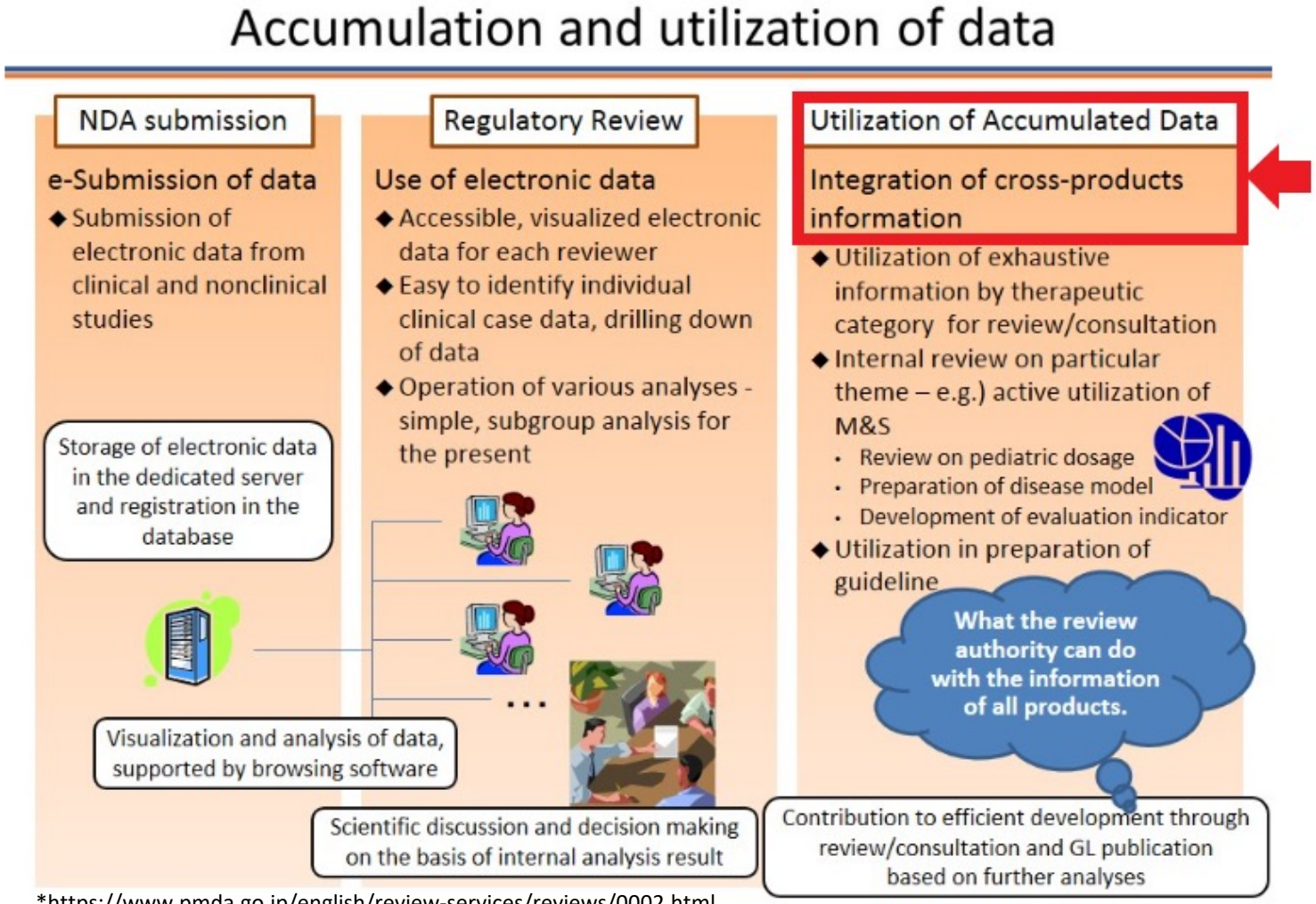
Impact of Disregarding Available Guidance

DISREGARDING CDISC TAUGS AND PHUSE GUIDANCE



*https://www.pmda.go.jp/english/review-services/reviews/0002.html

Conclusion

- Relying solely on the SDTM Implementation Guide is not sufficient
- Preparers of SDTM datasets need to be aware (and follow) guidance from:
  - Regulatory Agencies
  - CDISC (such as TAUGs, QRS Supplements, errata, etc.)
  - PHUSE
  - Other organizations
- There are real impacts to disregarding guidance from these organizations

Questions?

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